Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

DATE: May 16, 2000

WARNING LETTER
2000-DT-23

Howard F. Terrill, D.V.M.
President
Manchester Veterinary Clinic & Supply, P.C.
11798 North Street Road, # 13
North Manchester, Indiana 46962

Dear Dr. Terrill:

An investigation of your veterinary clinic on August 3, 13 and 16, 1999, by the Food and Drug Administration (FDA) revealed serious deviations from the Federal Food, Drug, and Cosmetic Act.

Our investigation revealed your clinic is prescribing veterinary drugs to approximately [redacted] veal farms in Pennsylvania, and that a veterinarian from your clinic visits these farms infrequently. FDA does not find that your clinic has a valid veterinarian/client/patient relationship (VCPR) with the Pennsylvania veal farms. A valid veterinarian/client/patient relationship has been defined in Title 21 of the Code of Federal Regulations [21 CFR 530(i)] as one in which:

1. A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;

2. There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

3. The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

You are selling prescription veterinary drugs which are misbranded within the meaning of Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act [the Act] in that they do not have adequate directions for use.

> "Adequate directions for use" according to Title 21 of the Code of Federal Regulations (CFR) 201.5 means adequate directions under which the layman can use a drug safely and for the purposes for which is was intended. Prescription drugs, according to Section 503 of the Act, are those which are not safe for animal use because of their toxicity or potentiality for harmful effect except under the professional supervision of a licensed veterinarian. They do not bear adequate directions for use by laypersons because they cannot be written.
>
> Within a valid VCPR, prescription animal drugs are exempt from adequate directions for lay use; the veterinarian's supervision can be substituted for the legal requirement that drugs be labeled with adequate directions for use. Without supervision, prescription drugs are misbranded because they lack adequate directions for the layperson to use them safely. You fail to provide appropriate supervision.

You are selling drugs for extra label use which do not meet the conditions established in 21 CFR 530, the Animal Medicinal Drug Use Clarification Act (AMDUCA), for legal extra label use. These drugs are in violation of 501(a)(5) of the Act in that they are new animal drugs which are unsafe within the meaning of section 512, and 502(f)(1) of the Act in that they do have adequate directions for use.

> Under 21 CFR 530, veterinarians are permitted to use drugs for extra-label use (ELU). The basis for any legal ELU as provided in 21 CFR 530.10 is the establishment of a valid veterinarian/client/patient relationship.

This is not intended to be an all-inclusive list of violations that may be present in your veterinary clinic. We request that you take prompt action to correct these violations. Failure to promptly correct these violations, or similar violations, may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

The Indiana Board of Animal Health has received a copy of this letter.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be directed to Sandra Williams, Compliance Officer, at the above address.

Sincerely,

John P. Dempster

John P. Dempster
Acting District Director
Detroit District

cc via Certified Mail: Jeffrey L. Pyle, D.V.M., Vice President
cc via Certified Mail: Alexander Cole, D.V.M.
cc via Certified Mail: Bret Marsh, DVM
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